

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2017-F-4399]

Zinpro Corp.; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; petition for rulemaking; amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that the Zinpro Corp. (Zinpro) has amended their pending petition proposing that the food additive regulations be amended to provide for the safe use of chromium DL-methionine as a nutritional source of chromium in cattle feed. The amendment provides for a change in the feeding rate.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-F-4399 for "Zinpro Corp.; Filing of Food Additive Petition (Animal Use)." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and

written/paper comments received, go to https://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville,

MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Cerrito, Center for Veterinary

Medicine, Food and Drug Administration (HFV-224), 7519 Standish Pl., Rockville, MD 20855,

240-402-6729, Chelsea. Cerrito@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 22, 2017 (82 FR

44367), FDA announced that Zinpro Corp., 10400 Viking Dr., suite 240, Eden Prairie, MN

55344 had filed a petition (FAP 2300) proposing to amend Title 21 of the Code of Federal

Regulations (CFR) in part 573 (21 CFR part 573) Food Additives Permitted in Feed and

Drinking Water of Animals to provide for the safe use of chromium DL-methionine as a

nutritional source of chromium in cattle feed. Zinpro has amended the petition by changing the

feeding rate.

Zinpro has submitted a revised environmental assessment which the Agency is placing on

public display at the Dockets Management Staff for public review and comment (see DATES

and ADDRESSES).

Dated: November 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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